November 6, 2018

Bio-Medical Research Ltd.
% Gerard J. Prud'homme
Partner
Hogan Lovells US LLP
Columbia Square, 555 Thirteenth Street, NW
Washington, DC 20004

Re: DEN170049
Trade/Device Name: Innovo
Regulation Number: 21 CFR 876.5330
Regulation Name: Transcutaneous electrical continence device
Regulatory Class: Class II
Product Code: QAJ
Dated: September 18, 2017
Received: September 18, 2017

Dear Gerard J. Prud'homme:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Innovo, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Innovo is a transcutaneous electrical stimulator indicated for the treatment of stress urinary incontinence in adult females.
>
> The Innovo is indicated for prescription use only.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Innovo, and substantially equivalent devices of this generic type, into Class II under the generic name transcutaneous electrical continence device.

FDA identifies this generic type of device as:

> **Transcutaneous electrical continence device.** A transcutaneous electrical continence device consists of cutaneous electrodes that are used to apply external stimulation to reduce urinary incontinence.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may

request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 18, 2017, FDA received your De Novo requesting classification of the Innovo. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Innovo into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Innovo can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Pain or tissue damage due to overstimulation	Non-clinical performance testing Software verification, validation, and hazard analysis Electrical safety testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Electrical shock or burn	Electrical safety testing Software verification, validation, and hazard analysis Labeling
Device failure due to electromagnetic interference	Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Labeling
Use error that may result in user discomfort, injury, or delay in treatment	Software verification, validation, and hazard analysis Labeling

In combination with the general controls of the FD&C Act, the transcutaneous electrical continence device is subject to the following special controls:

1. Non-clinical performance testing must characterize the electrical stimulation, including the following: waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, net charge per pulse, maximum phase charge at 500 ohms, maximum current density, maximum average current, and maximum average power density.

2. The patient-contacting materials must be demonstrated to be biocompatible.

3. Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, thermal safety, and mechanical safety of the device.

4. Software verification, validation, and hazard analysis must be performed.

5. Labeling must include the following:
    a. Instructions for use, including specific instructions regarding the proper placement of electrodes;
    b. A summary of electrical stimulation parameters; and
    c. Cleaning instructions and reuse information.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the transcutaneous electrical continence device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Purva Pandya at (240) 402-9979.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health